510(k) Summary

K120782

1. **SUBMITTER/510(K) HOLDER**

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Wallingford, CT 06492
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Date Prepared: March 4, 2013

MAR 2 0 2013

2. **DEVICE NAME**

Proprietary Name: QuikClot Interventional-A Hemostatic Bandage
Common/Usual Name: Hemostatic Dressing
Classification Name: Wound Dressing

3. **PREDICATE DEVICES**

- K060409 HemoHalt Hemostasis Pad Wound Dressing
- K112961 Scion Cardio-Vascular Clo-Sur PLUS
- K040208 TZ Medical Neptune Pad and Comfort Band(Interventional and Radial)
- K090620 QuikClot Interventional Dressings

4. **DEVICE DESCRIPTION**

The purpose of this 510(k) is to obtain a new indication for the previously cleared QuikClot Interventional Hemostatic Bandage subject of K090620. The new indication to be added to the previously cleared device is simply for compatibility with anticoagulant therapy. Therefore, the proposed indications for use are as follows: QuikClot Interventional-A Hemostatic Bandage is applied topically as an adjunct to manual compression and is indicated for the local management and control of surface bleeding from vascular access sites, percutaneous catheters or tubes utilizing introducer sheaths up to 7 Fr. in patients on drug/induced anti-coagulation treatment. QuikClot Interventional-A Hemostatic Bandage has been tested in clinical trials and its efficacy has been shown only in patients treated with the anti-coagulation medications: heparin, Clopidrogel bisulfate and warfarin. The efficacy of QuikClot Interventional-A Hemostatic Bandage in the presence of other anti-coagulation medications is not known. QuikClot Interventional-A Hemostatic Bandage has not been tested on patients with bleeding disorders due to underlying disease (liver, kidney or others) and is not indicated for these populations. This 510(k) was not submitted as a Special 510(k) Premarket Notification because a new indication has been added to the previously cleared indications for the QuikClot Interventional Hemostatic Bandage.

The QuikClot Interventional-A Hemostatic Bandage that is the subject of this submission is described in detail in K090620 in that it is made of a soft, white, kaolin-impregnated gauze. QuikClot® Interventional-A Hemostatic Bandage may be provided in a kit form that consists of a hemostatic pad and an adhesive bandage. The adhesive bandage is a 3M Tegaderm® bandage (K973036) or equivalent. The hemostatic pad is a hemostatic

dressing made of soft, white, kaolin impregnated gauze, configured in a 1 ½" long by 1 ½"wide by ½" thick multi-layer pad.

5. INTENDED USE

QuikClot Interventional-A Hemostatic Bandage is applied topically as an adjunct to manual compression and is indicated for the local management and control of surface bleeding from vascular access sites, percutaneous catheters or tubes utilizing introducer sheaths up to 7 Fr. in patients on drug/induced anti-coagulation treatment.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The QuikClot Interventional-A Hemostatic Bandage is substantially equivalent to the predicate devices with respect to device characteristics and intended use.

The QuikClot Interventional-A Hemostatic Bandage contains a hemostatic agent, kaolin. The formulation of the proposed and predicate QuikClot device is identical and the only modification is in the intended use and indications for use. The QuikClot Interventional-A Hemostatic Bandage and the predicate devices are equivalent in that they all contain a hemostatic agent that functions to stop bleeding in anticoagulated patients.

7. PERFORMANCE TESTING

Biocompatibility and performance testing have been included which supports the substantial equivalence of the proposed QuikClot Interventional-A Hemostatic Bandage. Specifically, the following testing has been performed to support K090620 and the original QuikClot Hemostatic Dressings subject of K072474:

Cytotoxicity	L929 Neutral Red Uptake according to ISO 10993-5:2009 'Biological Evaluation of Medical Devices, Part 5: Tests for In Vitro Cytotoxicity'	Non-cytotoxic
Irritation	ISO 10993-10:2002, Amendment 1:2006, 'Biological Evaluation of Medical Devices, Part 10; Tests for Irritation and Delayed-Type Hypersensitivity'	Non-irritating
Sensitization	ISO 10993-10:2002, Amendment 1:2006, 'Biological Evaluation of Medical Devices, Part 10; Tests for Irritation and Delayed-Type Hypersensitivity'	Non-sensitizing
Systemic Injection (intraperitoneal)	International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity (ISO).	Non-toxic
Systemic Injection (intravenous injection)	International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity (ISO).	Non-toxic
Genotoxicity	ISO 10993-3:2003 Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	Non- mutagenic
Repeat Exposure Systemic Toxicity	Custom Designed Test Program	Non-toxic

8. SAFETY AND EFFICACY

Animal testing has been performed to demonstrate compatibility of the QuikClot Hemostatic Dressing and anticoagulant therapy. This testing showed that the QuikClot Hemostatic Dressing is used safely and effectively in the swine animal model on drug/induced anticoagulant therapy.

TABLE 1

Study Name/Description	Pre-clinical evaluation of QuikClot in a swine model of anti-coagulation
Objective	To evaluate the efficacy of Kaolin, the active ingredient in Z-Medica's QuikClot Combat Gauze in controlling bleeding in animals treated with common drugs such as Coumadin and Plavix.
Number of sites/investigators (OUS/US)	One site (US) and one investigator
Number of animals **Number of wounds**	Ten pigs were divided in 2 groups (five animals each): One group received Plavix at 75 mg/day orally for > 5 days. The second group received daily doses of Coumadin until INR was > 3. 187 intra-abdominal vascular injuries (splenic, liver and mesenteric) were tested. Injuries consisted of surgically inflicted wounds with mixed arterial and venous bleeding. The size of the wounds was 5cm in length and 3-5 mm in depth for liver and spleen, and 2 mm of depth for the mesentery.
Procedure	In combination with manual pressure, QuikClot was applied to a series of wounds at the level of the liver, spleen, mesentery and femoral artery and compared to standard surgical gauze. The study was prospective, open label, randomized 1:1 between QuikClot and control. Manual compression was applied over the wounds for 5 minutes and then released.
Success/Failure criteria	Success = 100% complete bleeding cessation within 5 minutes Failure = persistent bleeding at 5 minutes
Study results	Animals treated with Coumadin and QuikClot showed successful control of bleeding in 94.5% of wounds. Animals treated with Coumadin and control gauze showed control of bleeding in 24%. Animals treated with Plavix and QuikClot showed successful control of bleeding in 91.2% of wounds. Animals treated with Plavix and control gauze showed control of bleeding in 29.7% of wounds%.

QuikClot Combat Gauze versus Control in Coumadin treated Pigs (n=5)

	Pass	Fail	Total
Test	52	3 p<0.001	55
Control	9	29 p<0.001	38
			93

QuikClot Combat Gauze versus Control in Plavix treated Pigs (n=5)

	Pass	Fail	Total
Test	52	5 p<0.001	57

	Control	11	26 p<0.001	37
				94
Adverse events	No animals died because of bleeding. The wounds where QuikClot did not control bleeding completely within 5 minutes required some additional manual compression time.			

Additional Clinical Data/References:

Several peer reviewed clinical publications support the use of QuikClot Interventional Hemostatic Bandage in human patients on drug/induced anticoagulant therapy.

TABLE 2

Study Name/Description	**Trabattoni D, et al.** ***A New Kaolin-based Hemostatic Bandage Use after Percutaneous Coronary Diagnostic and Interventional Procedures*****; Internat J Cardiol; 2010 Nov 172.**
Number of sites/investigators (OUS/US)	One site (OUS). Three investigators
Number of subjects	40 subjects
Inclusion/ **Exclusion**	Patients undergoing diagnostic angiography or percutaneous coronary intervention via a femoral artery approach Not described in publication
Procedure	Prospective single arm pilot trial of QuikClot Interventional Hemostatic Bandage in cardiac catheterization. Introducer sheath size 6 Fr (90%) or 7 Fr (10%) Femoral artery sheath removed once the ACT < 180 seconds All patients were treated with QuikClot Interventional Hemostatic bandage after arterial sheath removal
Study endpoints and assessment protocol	Complete 100% bleeding cessation at 5 minutes and safe ambulation at 4 hours
Duration of follow-up	30 days
Patient Demographics	75% male Mean Age = 68+/- 11 years
Patient condition (means of achieving anticoagulation, level of anticoagulation)	Patient undergoing diagnostic angiogram (62%) vs. Percutaneous Coronary Intervention PCI (38%) via femoral artery approach 6F (90%) 7F (10%). QuikClot n=40 LMW Heparin: 2.5% Aspirin + Clopidogrel: 27.5% Aspirin: 60% Aspirin + Warfarin: 5% IV Heparin: 38% No anticoagulation: 5%
Study results	Mean ACT value at hemostasis 138 + 24 seconds (range 95-186 seconds) Mean cumulative hemostasis time 4.9±1.05 min • Diagnostic procedures 4.2±0.9 min • Interventional procedures 5.3±0.95 min Ambulation time 4 h for all patients
Adverse events	One PCI patient required extra compression time to achieve hemostasis and developed a small (< 5cm) hematoma

TABLE 3

<table>
<tr><td>Study Name/Description</td><td>Trabattoni D, et al. A New Kaolin-based Haemostatic Bandage Compared with Manual Compression for Bleeding Control after Percutaneous Coronary Procedures; Eur Radiol, 2011 Aug 21(8): 1687-91.</td></tr>
<tr><td>Number of sites/investigators (OUS/US)</td><td>One site (OUS), six investigators</td></tr>
<tr><td>Number of subjects</td><td>200 subjects
Prospective randomized trial of QuikClot(n=100) vs. manual compression (n=100)</td></tr>
<tr><td>Inclusion/

Exclusion</td><td>Undergoing angiography or percutaneous coronary intervention via a femoral approach

Patients with baseline INR > 1.4 excluded

Patients who had previous arterial access at the same femoral site within 30 days excluded</td></tr>
<tr><td>Procedure</td><td>Femoral arterial sheath removed once the ACT ≤ 180 seconds

Patients randomized to receive QCI gauze or manual compression after femoral sheath removal

Patient ambulation at 4 hours.</td></tr>
<tr><td>Study endpoints and assessment protocol</td><td>Complete 100% bleeding cessation at 5 minutes and safe ambulation at 4 hours</td></tr>
<tr><td>Duration of follow-up</td><td>30 days</td></tr>
<tr><td>Patient demographics</td><td>Male 70% QuikClot vs. 60% Control
Mean age (years) 65.7±13 vs. 73.6±6.2
Weight (Kg) 73.9±12 vs. 71.2±15

Diagnostic procedure (n=98) vs. Percutaneous coronary intervention (n=102)

Introducer sheath size 6 Fr (90%) or 7 Fr (10%)</td></tr>
<tr><td>Patient condition (means of achieving anticoagulation, level of anticoagulation)</td><td>
<table>
<tr><td></td><td>QuikClot</td><td>Control</td></tr>
<tr><td>LMW Heparin</td><td>4%</td><td>2%</td></tr>
<tr><td>Aspirin + Clopidogrel</td><td>29%</td><td>26%</td></tr>
<tr><td>Aspirin</td><td>60%</td><td>60%</td></tr>
<tr><td>Aspirin + Warfarin</td><td>7%</td><td>3%</td></tr>
<tr><td>IV Heparin</td><td>51%</td><td>49%</td></tr>
<tr><td>No anticoagulation</td><td>0%</td><td>9%</td></tr>
</table>
</td></tr>
<tr><td>Study results</td><td>Mean ACT value at hemostasis 146 + 24 seconds (range 98 – 198 seconds)

Hemostasis with QCI bandage = 5.4 ± 1.5 min
Hemostasis with manual compression = 25 ± 15 min p<0.001

No hemostasis failure in either group</td></tr>
<tr><td>Adverse events</td><td>Major Bleeding: 1 patient in each group

Haematoma, > 5 cm
1* pt (QuikClot) vs. 2 pts (control)

Pseudoaneurysm
1* pt (QuikClot) vs. 1 pt (control)
*Same patient</td></tr>
</table>

TABLE 4

<table>
<tr><td>Study Name/Description</td><td>Politi L, et al. Randomized Clinical Trial on Short-Time Compression with Kaolin Filled Pad: A New Strategy to Avoid Early Bleeding and Subacute Radial Artery Occlusion after Percutaneous Coronary Intervention; J Internat Card; 2011; Vol 24; 65-72</td></tr>
<tr><td>Objective</td><td>To evaluate the occurrence of 24 hour radial artery occlusion and the rate of bleeding of a novel hemostatic device for radial closure after percutaneous interventions, in adjunct to short-time compression.</td></tr>
<tr><td>Number of sites/investigators (OUS/US)</td><td>One site (OUS). Ten investigators</td></tr>
<tr><td>Number of subjects</td><td>120 subjects divided in 3 groups:
Group 1 (QuikClot n=50)
Group 2 (control short time – 15 minute compression n=20)
Group 3 (control 2 hours compression time n=50)</td></tr>
<tr><td>Inclusion/

Exclusion</td><td>All patients undergoing transradial elective diagnostic or interventional coronary procedures between November 1, 2009 and January 31, 2010

Abnormal Allen's test before puncture
Failure to provide written informed consent</td></tr>
<tr><td>Procedure</td><td>QuikClot was applied to the radial artery over the sheath which was then removed. Pressure was maintained for 15 minutes and then completely relaxed.</td></tr>
<tr><td>Study endpoints and assessment protocol</td><td>The main end-point was subacute Radial Artery Occlusion (RAO)

The secondary end-point was failure of the closure technique (death, MI or major bleeding occurring in hospital)

Groups 1 and 2: 15 minute assessment for bleeding
Group 3: 2 hour assessment for bleeding
All groups: Radial artery patency assessed at 24 hours using Barbeau's Test</td></tr>
<tr><td>Duration of follow-up</td><td>Until patient discharge and follow-up visit. Follow-up at 6 months was done for patients who developed RAO</td></tr>
<tr><td>Patient demographics</td><td>Age (years) Group 1 = 64.16 ± 11.53, Group 2 = 61.30 ± 14.22, Group 3 = 59.72 ± 14.23 (p=N/S)
Male 37 (74%), 14 (70%), 36 (72%) (p=N/S)
Weight (kg) 76.42 ± 11.13, 80.00 ± 14.96, 82.02 ± 13.26 (p=N/S)</td></tr>
<tr><td>Patient condition (means of achieving anticoagulation, level of anticoagulation)</td><td>
<table>
<tr><td></td><td>QuikClot</td><td>Control Group 1</td><td>Control Group 2</td></tr>
<tr><td>Aspirin</td><td>46 (92%)</td><td>19 (95%)</td><td>50 (100%)</td></tr>
<tr><td>Clopidogrel</td><td>10 (20%)</td><td>2 (10%)</td><td>11 (22%)</td></tr>
<tr><td>LMW Heparin</td><td>8 (16%)</td><td>5 (25%)</td><td>5 (10%)</td></tr>
<tr><td>Warfarin</td><td>6 (12%)</td><td>5 (25%)</td><td>5 (10%)</td></tr>
<tr><td>IV heparin</td><td>100%</td><td>100%</td><td>100%</td></tr>
<tr><td>No anticoagulation</td><td>0%</td><td>0%</td><td>0%</td></tr>
<tr><td colspan="4">Several patients received multiple therapies</td></tr>
</table>
</td></tr>
<tr><td>Randomization Assignment</td><td>Based on computer generated randomization list patient received one of the three treatment groups below:

Group 1: Compression of radial artery using QuikClot Interventional hemostatic pad with folded gauze over the pad and taped for 15 minutes; Compression dressing then removed</td></tr>
</table>

	leaving the QuikClot pad which was secured using Tegaderm dressing for 2 hours. Group 2: Compression of radial artery using folded gauze which was taped for 15 minutes; Compression dressing was then removed leaving the sterile gauze which was secured using Tegaderm dressing for 2 hours Group 3: Direct compression of the site of puncture with a folded sterile gauze wrapped with tape and maintained for 2 hours
Study results	While a total of 150 patients were planned to be enrolled, the study stopped enrolling group 2 subjects after the 20th patient due to unethically high rates of bleeding. Radial Artery Occlusion None of the patients enrolled in Group 1(QuikClot) developed RAO the main outcome variable. Among patients enrolled in Group 2 RAO occurred in 1 case (5%) and among Group 3 in 5 cases (10%) ($p = 0.05$)
Adverse events	Active bleeding after compression removal Group 1: 10 patients (20%) Group 2: 18 (90%) Group 3: 1 (2%) ($p < 0.001$) In all cases, hemostasis was achieved with a supplementary compression for 2 hours that did not produced any RAO in Group 1

Post Market Data:

One hundred and thirty-eight Product Evaluation Forms were received from several health care institutions in the US where the QuikClot products were used for patients who were on anticoagulant medications. Seventy one percent of the patients were on anticoagulants. The QuikClot Dressings demonstrated a 96% success rate in controlling bleeding in treated subjects within the expected amount of time. There was a 4% rate of reported residual oozing which required additional manual compression time and 1% reported complications which are commonly reported for Interventional procedures. Ninety-three % of respondents indicated that QuikClot Interventional improved the outcome of their procedures and 95% reported that QuikClot products saved them time. A total of 97.4% of users would use QuikClot products again. Only 2 adverse events were reported and they were both in non-anticoagulant evaluations. One was reported as a small hematoma and the other was described as requiring 6 minutes to achieve hemostasis instead of 5 minutes.

9. CONCLUSION

Z-Medica believes that based on the indications for use, technological characteristics, and comparison with predicate devices the QuikClot Interventional-A Hemostatic Bandage has been shown to be substantially equivalent and is safe and effective for its intended use for patients on drug/induced anti-coagulation treatment utilizing heparin, Clopidrogel bisulfate or warfarin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Z-Medica, Corporation
% Ms. Sheila Wallin, RT, CRA
Vice President of Clinical and Regulatory Affairs
4 Fairfield Boulevard
Wallingford, Connecticut 06492

March 20, 2013

Re: K120782
Trade/Device Name: QuikClot Interventional-A Hemostatic Bandage
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 25, 2013
Received: February 01, 2013

Dear Ms. Wallin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120782

Device Name: QuikClot Interventional-A Hemostatic Bandage

Indications for Use:

QuikClot Interventional-A Hemostatic Bandage is applied topically as an adjunct to manual compression and is indicated for the local management and control of surface bleeding from vascular access sites, percutaneous catheters or tubes utilizing introducer sheaths up to 7 Fr. in patients on drug/induced anti-coagulation treatment.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use__ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K120782